DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Office of Pediatric Therapeutics
Room 4B-44, HFG-2
5600 Fishers Lane
Rockville, MD 20857

June 14, 2004

Michael M. Gottesman, MD
Deputy Director for Intramural Research
National Institutes of Health
10 Center Drive M.C. 1381
Bldg. 1, Room 114
Bethesda, MD 20892

Subject: **FDA Review under 21 CFR 50.54 of Protocol Entitled "Effects of a Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder; A Functional Magnetic Resonance Study"**

Re: Notification of FDA Jurisdiction over Clinical Investigation

Dear Dr. Gottesman:

This letter is to notify you that the Office of Human Research Protection (OHRP) at the Department of Health and Human Services forwarded the above- referenced protocol to the Food and Drug Administration (FDA) to make a preliminary determination as to whether the above-referenced study is regulated by FDA, and therefore whether it is subject to 21 CFR Part 50, Subpart D, "Additional Safeguards for Children in Clinical Investigations." FDA has completed its assessment of the proposed study and determined it is a clinical investigation regulated by the FDA under sections 505(i) of the Federal Food, Drug, and Cosmetic Act. Accordingly, it must be conducted in compliance with the requirements set forth in 21 CFR Parts 56 and 50, including Subpart D of Part 50.

Your April 20, 2004 letter to OHRP stated that the institutional review board that reviewed the above-referenced protocol concluded that the protocol presented an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, but was not otherwise approvable. Therefore, because the protocol is a clinical investigation regulated by FDA and subject to 21 CFR 50.54, FDA will be consulting with a panel of experts, in conjunction with OHRP, to review the protocol.

Your participation in this process will be critical and we will be communicating with you further about the process and timing of this important activity. Should you have any questions or wish to discuss this issue in the meantime please contact Ms. Terrie Crescenzi or Dr. Sara Goldkind at 301-827-9218.

Sincerely,

Dianne Murphy, M.D.
Director
Office of Pediatric Therapeutics
Office of the Commissioner

cc: Dr. Donald Rosenstein, NIMH, NIH
Dr. Murray Lumpkin, FDA
Dr. Steven Galson, CDER, FDA
Dr. Robert Temple, CDER, FDA
Dr. Russell Katz, CDER, FDA
Dr. Daniel Shultz, CDRH, FDA
Dr. Joann Less, CDRH, FDA
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